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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,014	04/07/2004	Matthew J. Banet	A-0003	3013

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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary	Application No.	Applicant(s)	
	10/709,014	BANET, MATTHEW J.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-11,14 and 18-25* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-11,14 and 18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/3/04,4/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Objections

Claims 1 and 9 are objected to because of the following informalities:

On line 6 of claim 1, "generates" should be replaced with "generate";

On line 1 of claim 9, "claim 8" should be replaced with "claim 7" since claim 8 lacks sufficient antecedent basis for "the first optical source" and "the second optical source", but claim 7 has sufficient antecedent basis for these limitations;

Appropriate correction is required.

Terminal Disclaimer

The terminal disclaimer filed on 8/22/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application No. 10/709015 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Election/Restrictions

Newly submitted claim 21 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally examined claims included claims drawn to an embodiment comprising a hand-held component wherein at least the optical module or the electrical sensor is incorporated into the hand-held component (see original claims 15-17). The originally examined claims did not include claims drawn to a second embodiment including a body-worn patch wherein the

optical module and electrical sensor are incorporated into the body-worn patch, as currently claimed in claim 21.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-6, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,788,634 to Suda et al. in view of US Patent No. 5,649,543 to Hosaka et al. Suda teaches a hand-held device for monitoring a patient's blood pressure comprising a removable hand-held component 1-3 configured to be held proximal to the patient's skin (figs. 1 & 4; col. 2, lines 49-57 of Suda). An optical module 4, 5 is mounted on the hand-held component 1-3 comprising an optical source component 4 and a first optical sensor 5 configured to generate a first set of information when the hand-held component is held proximal the patient's skin (figs. 1 & 4; col. 1, lines 21-37; col. 2, line 54-col. 3, line 22 of Suda). An electrical component 6, 7 is mounted on the hand-held component 1-3 and comprises an electrode pair 6, 7

configured to generate a second set of information when the hand held component 1-3 is held proximal the patient's skin (figs. 1 & 4; col. 1, lines 21-37; col. 2, line 57-col. 3, line1; col. 3, lines 25-30 of Suda). A processing module (col.3, lines 20-21 of Suda) is configured to receive the first and second sets of information and calculates a blood pressure based on the time difference between components of the first and second set of information (col. 1, lines 21-37 of Suda). Suda fails to describe the details of the processing module, particularly with respect to the exact method of determining blood pressure from the time difference.

However, Hosaka teaches a blood pressure monitoring device comprising a processing module, configured to receive a first set of data from an optical module and a second set of data from an electrical sensor. A processor 1 of the processing module calculates a time difference between components of the first set of information and the second set of information and compares the time difference to a mathematical model to calculate a blood pressure value (figs. 1 & 4; col. 7, lines 4-46; col. 8, line 40-col. 9, line 15 of Hosaka). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the processing module of Hosaka as that of Suda, since Suda teaches a blood pressure monitoring device comprising a processing module for determining blood pressure and Hosaka discloses an appropriate such processing module.

Regarding claims 2 and 4, the electrical sensor is a sensor that generates the second set of information in response to a body-generated electrical signal (col. 3, lines 25-27 of Suda). With further regard to claim 4, the electrical sensor is configured to

generate a time-dependent electrical waveform in response to the body-generate electrical signal (col. 1, lines 27-28; col. 3, lines 25-27 of Suda).

Regarding claims 5 and 6, the processing module further comprises an analog-to-digital converter 3 (fig. 1; col. 7, lines 54-63 of Hosaka). With further regard to claim 6, the electrical sensor is in electrical contact with the A/D converter (fig. 1 of Hosaka).

Regarding claim 22, the hand-held device comprises a pressure-delivering component configured to apply a pressure to the patient's skin, where the optical module generates the first set of information while the pressure is applied to the patient's skin (fig. 4; col. 2, lines 49-65; col. 3, lines 1-12 of Suda)

Regarding claim 23, the method of measuring blood is inherently disclosed in the description of the apparatus for monitoring blood pressure of Suda in view of Ogura, wherein the hand-held component, as described is provided proximal the patient's skin, a measurement is initiated wherein the first and second sets of information are generated (col.1, lines 21-37 of Suda) and the information is processed to calculate a blood pressure value (col. 1, lines 21-37l of Suda; col. 8, line 5-col. 9, line 11 of Ogura).

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suda in view of Hosaka, as applied to claims 1, 2, 4-6, 22, and 23 above, and further in view of US Patent No. 6,616,613 to Goodman et al. Suda, as modified, fails to describe the light emitting and receiving device or the processing of its signal in detail. However, Goodman teaches a blood pressure measuring device comprising a light emitting and receiving device 12 for obtaining pulse waves for use in blood pressure determination.

The light emitting and receiving device 12 comprises a red LED (light emitting diode) and an infrared LED and two photodiodes (col. 90, line 57-col. 10, line 24; col. 13, lines 4-25 of Goodman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the device Goodman with that of Suda, since Suda teaches using a light emitting and receiving device to obtain a pulse wave signal, and Goodman teaches an appropriate such light emitting and receiving device.

Regarding claims 9-11, the photodiode is configured to generate a photocurrent after detecting radiation generated by the first optical source and the second optical source (col. 10, line 49-col. 11, line 7 of Goodman). With further regard to claim 10, the processing module further comprises an A/D converter configured to receive and process the photocurrent (fig. 2, col. 10, lines 63-65 of Goodman; fig. 1; col. 8, lines 4-10 of Hosaka). With further regard to claim 11, the processing module comprises firmware that processes the photocurrent to generate a time-dependent optical waveform (col. 9, line 57-col. 10, line 7; col. 10, line 62-col. 11, line 7; col. 11, line 66-col. 12, line 21 of Goodman).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suda, in view of Hosaka as applied to claims 1, 2, 4-6, 22, and 23 above, and further in view of US Patent No. 6,537,225 to Mills. Suda, as modified, lacks computer readable firmware that processes the first set of information to additionally determine pulse oximetry and heart rate. However, Mills teaches a blood pressure measuring device comprising computer readable firmware that processes information from an optical module to

additionally determine pulse oximetry and heart rate (col. 8, lines 12-25; col. 15, line 52-col. 16, line 6; col. 16, lines 38-41 of Mills). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the device of Mills with that of Suda, as modified by Hosaka since Mills shows heart rate, blood pressure, and oxygen saturation of the blood to be primary and critical vital signs that indicate the health of patients (col. 1, lines 21-39 of Mills).

Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suda in view of Hosaka, as applied to claims 1, 2, 4-6, 22, and 23 above, and further in view of US Patent No. 4,718,428 to Russell et al. Suda, as modified, teaches an input member 7 for inputting a blood pressure value Po for calibration but fails to describe the input member in detail (fig. 1; col. 8, lines 12-23 of Hosaka). However, Russell teaches a blood pressure monitor comprising a processor, wherein information may be input to the processor via a serial interface (col. 12, line 22-25 of Russell). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a serial interface as the input member of Suda, as modified by Hosaka, since Suda, as modified, teaches using an input means, and Russell discloses a serial interface as being an appropriate such input means.

Claims 18-20, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suda in view of Hosaka, as applied to claims 1, 2, 4-6, 22, and 23 above, and further in view of US Patent No. 6,095,985 to Raymond et al. Suda, as

modified, teaches that the processor may output data to an external device via output connector 12 but fails to describe the connector (fig. 1; col. 9, line 20-23 of Hosaka). However, Raymond teaches that a physiological monitoring device may output information using a modem that is connected to the monitor by a serial interface (fig. 1; col. 5, lines 1-14 of Raymond). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the system of Raymond with the device of Suda, as modified by Hosaka, since Suda, as modified teaches outputting information to an external device via an output connector, and Raymond teaches outputting information using a serial interface and a modem to the internet as an appropriate means and method of outputting information. Raymond further teaches that outputting such physiological information to the Internet so that the information may be uploaded to a database is useful to track and assess general health over time as a diagnostic tool (col. 2, lines 5-24 of Raymond).

Regarding claim 20, the serial interface is clearly capable of accepting any information for output, wherein the term "calibration" is merely a designation of "intended use" and fails to patentably distinguish over the prior art.

Regarding claim 25, the modem transmits information to an Internet accessible computer system (col. 5, lines 20-27; col. 28, lines 27-59; col. 29, lines 26-27 and 30-52; col. 30, lines 5-8 of Raymond).

Response to Arguments

Applicant's arguments with respect to claims 1,2,4-11,14,18-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/pm/

Patricia Mallari
Patent Examiner
Art Unit 3736

/Robert E. Pezzuto/